

Message Text

UNCLASSIFIED

PAGE 01 STATE 232682

67

ORIGIN HEW-08

INFO OCT-01 EA-07 ISO-00 SCI-01 RSC-01 /018 R

66616

DRAFTED BY: DHEW/FDA: JRWEINROTH, M.D.

11/21/73 34480

APPROVED BY: SCI:MSBEAUBIEN (REC. 11/26/73)

DHEW/OIH: MACODDING

SCI/SA:RYODER(INFO)

EA/J:RDANKERT

----- 095320

R 272212Z NOV 73

FM SECSTATE WASHDC

TO AMEMBASSY TOKYO

UNCLAS STATE 232682

E.O. 11652: N/A

TAGS: TPHY, ETRD, TBIO, JA

SUBJ: VOLUNTARY RECALL ABBOTT HEPATITIS ASSOCIATED ANTIBODY
(ANTI-AUSTRALIA ANTIGEN).

1. FDA ADVISES THAT THE DRUG PRODUCT, HEPATITIS ASSOCIATED ANTIBODY (ANTI AUSTRALIA ANTIGEN) AUS-TECT FOR CEP TEST IS BEING RECALLED BY ABBOT LABORATORIES FROM THE MARKET DUE TO LOSS OF POTENCY OF THE TWO LOTS INVOLVED. THE FIRM DETECTED THE PROBLEM DURING TESTING IN THE FIRST WEEK OF OCTOBER, 1973 AND RECALLED BOTH LOTS TO USER LEVEL BY SEPARATE LETTERS, DATED OCTOBER 31, 1973. THE FIRM'S LETTER REQUESTED THAT THE PRODUCT BE QUARANTINED AND HELD UNTIL THESE LOTS COULD BE REPLACED BY FRESH STOCK.

2. THIS RECALL REPRESENTS A PRIORITY SITUATION, THE CONSEQUENCES OF WHICH ARE POTENTIALLY HAZARDOUS TO HEALTH EVEN THOUGH NO DEATHS OR INJURIES HAVE BEEN REPORTED TO DATE.

PRODUCT:

ABBOT HEPATITIS ASSOCIATED ANTIBODY (ANTI AUSTRALIA ANTIGEN)

TRADE NAME - AUS-TECT FOR CEP TEST

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 232682

LOT NUMBERS:

I ML VIALS: LIST #9033-01
MASTER LOT 28-013-BW
ANTIBODY LOT Z730330
5 ML VIALS: LIST 9026-02
MASTER LOT 28-051-BW
ANTIBODY LOT Z730428

FIRM:

ABBOTT SCIENTIFIC PRODUCTS DIVISION
ABBOTT LABORATORIES
NORTH CHICAGO, ILLINOIS

FOREIGN DISTRIBUTION:

DAINIPPON PHARMACEUTICAL COMPANY, LTD.
25 DOSHOMACHI 3-CHOME
HIGASHI-KU
OSAKA 541 JAPAN
50 X 1 ML VIALS ON JUNE 22, 1973
1000 X 1 ML VIALS ON JUNE 26, 1973

3. POST REQUESTED TO INFORM HOST GOVERNMENT DRUG CONTROL
AUTHORITIES FOR SUCH ACTION AS THEY DEEM APPROPRIATE. END
KISSINGER

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, COMMUNICABLE DISEASES
Control Number: n/a
Copy: SINGLE
Draft Date: 27 NOV 1973
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1973STATE232682
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA: JRWEINROTH, M.D.
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: n/a
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1973/newtext/t19731110/aaaaagvx.tel
Line Count: 82
Locator: TEXT ON-LINE
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: garlanwa
Review Comment: n/a
Review Content Flags:
Review Date: 04 FEB 2002
Review Event:
Review Exemptions: n/a
Review History: RELEASED <04-Feb-2002 by elbezefj>; APPROVED <14 MAR 2002 by garlanwa>
Review Markings:

Declassified/Released
US Department of State
EO Systematic Review
30 JUN 2005

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: VOLUNTARY RECALL ABBOTT HEPATITIS ASSOCIATED ANTIBODY (ANTI-AUSTRALIA ANTIGEN).
TAGS: TPHY, ETRD, TBIO, JA, US
To: TOKYO
Type: TE
Markings: Declassified/Released US Department of State EO Systematic Review 30 JUN 2005